

REMARKS/ARGUMENT

Claims 27-44, and 47-48 are cancelled without prejudice.

Claim 45 has been amended to convert it into an independent claim by incorporating therein the limitations of cancelled claims 27-30. Further support can be found at paragraphs [0020], [0062], [0089], [0095], [0100] and [0104] of published patent application US 2007/0141143.

New claims 53-62 have been added. Support for claims 53-56 is in paragraphs [0021], [0062] and [0063]. Support for claims 58, 59, 60, 61 and 62 is in the limitations of cancelled claims 27, 28, 35, 36 and 37, respectively. Additional support for the 10 wt% limitation in claim 60 is found in paragraph [0026].

Accordingly, no new matter has been introduced by the foregoing amendments.

Claims 28, 30, 35-37, 39, and 40 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite. These claims have been cancelled, making this rejection moot.

Claims 27-44 stand rejected under 35 U.S.C. 102(b) as being anticipated by Infeld WO 02/089835. These claims have been cancelled, making this rejection moot.

Claims 27-30 and 45-48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Infeld in view of Beyerinck et al. US 6,763,607. Claims 27-30 and 47-48 have been cancelled, making these rejections moot. The rejection of claims 45-46 is traversed for the following reasons.

In order to establish obviousness, the Office must establish motivation to modify a prior art reference to achieve the claimed invention and the rationale for such motivation must be clearly articulated. *KSR Int'l Co. v. Teleflex, Inc.*, 82 USPQ 2d 1385, 1396 (Sup Ct 2007).

In support of her contention of obviousness, the Examiner states that one of the goals of Infeld is to "enhance the bioavailability and dissolution of nelfinavir," pointing to

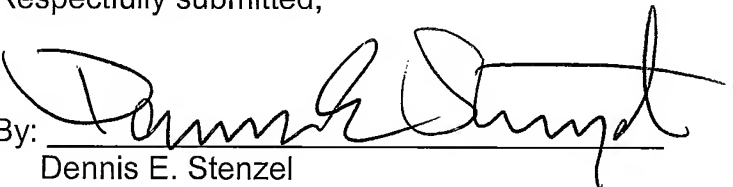
page 3, lines 16-17 and page 4, lines 25-26 of the reference. While it is agreed that Infeld's composition of amorphous nelfinavir mesylate melt granulated with a poloxamer shows "significant improvement" in the dissolution rate of the drug, the bioavailability is merely stated to be "satisfactory." Page 4, lines 25-26. At best then, this means that one of ordinary skill would understand from Infeld that the inclusion of a poloxamer with the particular form (amorphous and melt-granulated) of the drug merely yields satisfactory bioavailability and does not improve it, contrary to the Examiner's assertion.

The Examiner concedes that Infeld does not disclose concentration-enhancing polymers as claimed in claims 45-46, but relies on Beyerinck to supply the deficiency, citing column 13, line 49, column 17, lines 16-45 and claim 20 of Beyerinck. But at best Beyerinck teaches the formation of solid amorphous dispersions of a drug and a blend of poloxamer and one or more of the five cellulosic polymers recited in claim 46.

Independent claim 45, as amended, is directed to a composition comprising a mixture that is not a molecular dispersion of two components: (1) particles comprising at least 75 wt% amorphous drug and a poloxamer, and (2) a concentration-enhancing polymer. Thus, following Beyerinck's teaching, one of ordinary skill would be motivated to make an amorphous dispersion of drug and a blend of poloxamer and a cellulosic polymer, which does not correspond to component (1) of independent claim 45. Accordingly, claims 45-46 are not obvious in view of the combination of Infeld and Beyerinck.

New claims 53-62 all ultimately depend from claim 45, and so are novel and unobvious with respect to the same combination of references.

Respectfully submitted,

By: 

Dennis E. Stenzel

Reg. No. 28,763

Telephone No.: (503) 278-3304

Fax No. (503) 227-4373